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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,091	10/17/2001	Akiko Kumagai	CIT1320-1	6755

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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	14

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,091	KUMAGAI ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *1-4,6 and 16-22* is/are withdrawn from consideration.

5)☒ Claim(s) *7* is/are allowed.

6)☒ Claim(s) *5 and 8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2001 and 11 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

DETAILED ACTION

This is the First Office Action on the Merits of the application filed 17 October 2001, which claims benefit of U.S. Provisional application 60/241,246 filed 17 October 2000. The preliminary amendments filed 11 February 2002, 3 June 2002, and 2 June 2003 have been entered.

Election/Restrictions

Applicant's election of Group II (claims 5 and 7-15) in Paper No. 13, filed 2 June 2003, is acknowledged. Because applicant did not distinctly and specifically point out errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-4, 6 and 16-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

In the instant case, the sequences disclosed in non-provisional application 09/982,091 as SEQ ID NO: 3 and 5 (i.e., the human nucleic acid sequences) were not disclosed in the parent provisional application 60/241,246. Therefore, to the extent that they read on the sequences set forth as SEQ ID NO: 3 or 5, the claims are afforded a priority date of 17 October 2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 8-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With regard to claim 5, the claim is directed to an isolated nucleic acid encoding a polypeptide having the functional limitation of specifically interacting with a chK1 protein and the structural limitations of an SQ/TQ motif, an isoelectric point of about 4.5 and at least one nuclear localization signal. An SQ/TQ motif is described in the paragraph bridging pages 6-7 of the specification as any serine or threonine residue adjacent to a glutamine residue. Thus the claims are generic to any nucleic acid encoding a protein that interacts specifically with chK1, has at least one serine or threonine next to a glutamine, has an isoelectric point of about 4.5 and comprises a nuclear localization signal.

The Guidelines for Written Description state, "when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus" (Federal Register, Vol. 66, No. 4, Column 2, page 71436). In the instant case, the disclosure provides two examples of polypeptides having the structural and functional limitations of the claims, i.e., human and Xenopus claspin polypeptides. However, given that the limitations of the claims encompass polypeptides of widely divergent structure, the disclosure of two homologous polypeptide sequences fails to reflect the variation within the claimed genus.

Beyond the disclosure of a representative number of species, the written description requirement for a claimed genus may be satisfied through sufficient disclosure of the relevant identifying characteristics of the genus (i.e., structure or other physical and/or chemical properties), by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics (see MPEP 2163 (ii)).

The structural limitations set forth in the claim do not adequately describe the claimed genus because they would be present in many functionally divergent polypeptides. Clearly there can be no common function ascribed to all proteins comprising a serine or threonine adjacent to a glutamine, having an isoelectric point of about 4.5 and at least one nuclear localization signal. Thus, the structural limitations are not relevant to the claimed genus because they do not define a protein having any specific function.

Although the claims recite a functional limitation (i.e., specifically interacting with a chK1 protein), there is no evidence that the structural limitations recited in the claim or described in the specification are in any way relevant to said functional limitation. Thus, there is no disclosed correlation between function and structure. It is not sufficient to define polypeptide solely by its principal biological property, (i.e., it specifically interacts with a chK1 protein) because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any polypeptide with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all nucleic acids encoding polypeptides that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)).

Claims 8 and 9 are directed to an isolated polynucleotide having at least 15 contiguous bases that hybridize to a polynucleotide encoding a polypeptide having an amino acid sequence as set forth in SEQ ID NO: 2 or 4 or a polynucleotide having a sequence set forth as SEQ ID

NO: 1 or 3 or fragments of SEQ ID NO: 3 and degenerate variants of the claimed poly nucleotides. Claims 11-15 are directed to an expression vector and host cell comprising the claimed polynucleotides and a method for producing a polypeptide using the claimed polynucleotides. As the Office interprets "having" as open (i.e., "comprising"), the claims encompass any polynucleotide comprising at least 15 continuous bases that hybridize to a polynucleotide comprising the disclosed polynucleotides. Because a polynucleotide that comprises a disclosed sequence also comprises undisclosed sequence, the claims encompass polynucleotides comprising 15 continuous bases that hybridize with some undisclosed sequence. Clearly these nucleic acids are not described in the specification. For this reason, when claiming a nucleic acid that hybridizes with a disclosed nucleic acid, the probe must be limited to consisting of the disclosed nucleotide sequence.

Furthermore, as the claims provide no limitation on hybridization conditions, the claims encompass any polynucleotide that comprises 15 continuous bases that hybridize under even very low stringency conditions. Given that even nucleic acids having very little structural similarity will hybridize under low stringency conditions, the claims encompass nucleic acids comprising 15 continuous bases having some low degree of structural similarity to the disclosed polynucleotides. Again, the disclosure clearly fails to describe the genus of claimed polynucleotides. For this reason, when claiming a polynucleotide that hybridizes with a disclosed polynucleotide the claim must specify hybridization conditions that require a structural similarity that is relevant to a disclosed function. For example, if the claimed polynucleotide is to function as a specific probe for a particular nucleic acid molecule, the hybridization conditions set forth in

the claim must be stringent enough to exclude nucleic acids that would not have the disclosed function.

Claim 10, part c, is directed to an isolated polynucleotide comprising a fragment of a nucleic acid comprising a sequence set forth as SEQ ID NO: 5 or a sequence complementary to SEQ ID NO: 5. Again, because the antecedent of the fragment is a polynucleotide comprising a disclosed sequence, the claim encompasses fragments of undisclosed sequence (i.e., fragments of the sequence comprised by the polynucleotide that are not SEQ ID NO: 5). When claiming a sequence that is a fragment of another sequence, the language used to limit the reference sequence must be closed in order to comply with the written description requirement of 35 U.S.C. §112, first paragraph.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of nucleic acids encompassed by the claims. Therefore, only nucleic acids comprising a nucleotide sequence that hybridizes under highly stringent conditions (page 12, paragraph [0044]) with a polynucleotide, wherein the sequence of said polynucleotide consists of (a) a sequence encoding SEQ ID NO: 2 or 4; (b) the sequence of (a), wherein T can be U; (c) a sequence which is complementary to the sequence of (a); (d) the sequence as set forth in SEQ ID NO: 1 or 3; or (e) degenerate variants of (a), (b), (c) or (d), and a fragment of a polynucleotide consisting of the sequence set forth as SEQ ID NO: 5 meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 8-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for embodiments of the claimed invention that are adequately described in the disclosure as set forth herein above, does not reasonably provide enablement for all polynucleotides comprising 15 continuous bases that hybridize with some undisclosed sequence; any polynucleotide that comprises 15 continuous bases that hybridize to one of the disclosed sequences; or fragments of undisclosed sequence. Furthermore, the disclosure is not enabling for fragments of a polynucleotide consisting of the sequence set forth as SEQ ID NO: 5 wherein the fragment is too small to have any specific function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Enabled uses for nucleic acids encoding claspin polypeptides and fragments thereof of sufficient size to encode epitopes or act as specific probes for nucleic acids encoding claspin polypeptides are found throughout the specification. However, the specification does not teach how to use polynucleotides that do not encode claspin polypeptides or do not hybridize with polynucleotides encoding claspin polypeptides. Nor does the specification provide a specific or substantial use for fragments of SEQ ID NO: 5 of 1, 2, 3, etc. nucleotides in length. Therefore, the skilled artisan would have to engage in undue trial and error experimentation to identify a use for the large number of nucleic acids encompassed by the claims that do not encode claspin polypeptides and do not hybridize with polynucleotides encoding claspin polypeptides. Thus, due to the lack of guidance in the specification or prior art with regard to how to use all

polynucleotides regardless of structure and function, it would require undue experimentation to practice the invention commensurate with the full scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite limitations as derivatives of some starting material (i.e., virus derived or plasmid derived vector). Without a clear statement of the process by which the starting material is derivatized it is not possible to know the metes and bounds of such a limitation because any given starting material can have many divergent derivatives depending on the process of derivatization. Amending the claims such that they are directed to the vector of claim 11, wherein the vector is a viral vector or plasmid vector would be remedial.

Claim 13 is additionally indefinite in being directed to the vector of claim 12, wherein the vector is plasmid-derived. Claim 12 is directed to a viral vector which is generally understood in the art to be distinct from a plasmid vector. Amending claim 13 to depend from claim 11 would be remedial.

Claim Rejections - 35 USC § 102

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Accession No. AL354864 (4 April 2001) available at http://www.ncbi.nih.gov/entrez/.

The sequence set forth as Accession No. AL354864 comprises sequence of at least 15 bases that hybridizes to a polynucleotide having the nucleotide sequence set forth in the instant application as SEQ ID NO: 3 and comprises sequence that is a fragment of SEQ ID NO: 5 (see especially nucleotides 39448-98284). Thus, the sequence disclosed in the art anticipates the instant claimed invention.

Claims 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by either one of Accession No. AP001261 (31 May 2000) or Accession No. G30470 (1996), both available at http://www.ncbi.nih.gov/entrez/.

The sequences set forth as Accession No. AP001261 and Accession No. G30470, comprise sequence of at least 15 bases that hybridizes to a polynucleotide having the nucleotide sequence set forth in the instant application as SEQ ID NO: 3 and comprises sequence that is a fragment of SEQ ID NO: 5 (see especially nucleotides 91697-91805 of Accession No. AP001261 and nucleotides 1-340 of Accession No. G30470). Thus, the sequence disclosed in the art anticipates the instant claimed invention.

Allowable Subject Matter

Claim 7 is allowed. The prior art does not teach a polynucleotide encoding the amino acid sequences set forth as SEQ ID NO: 2 or 4, or a polynucleotide comprising a sequence set forth as SEQ ID NO: 1 or 3. Thus, the claim is patentable over the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
August 2, 2003

JAMES KETTER
PRIMARY EXAMINER